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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,136	11/15/2001	Sharon T. Wong-Madden	NEB-20C2CD3	6015

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NEW ENGLAND BIOLABS, INC.
32 TOZER ROAD
BEVERLY, MA 01915

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT PAPER NUMBER

1652

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/003,136	WONG-MADDEN ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 10, and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 7, 10, and 11 are under consideration in this Office Action. New rejections and new grounds for rejection are stated in the instant Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
3. Claims 7, 10, 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are genus claims that are directed toward any fucosidase, mannosidase, xylosidase, glucosidase, galactosidase, N-acetylglucosaminidase, and hexosaminidase of any amino acid sequence and structure obtainable from any *Xanthomonas* species. The scope of the claims includes many exoglycosidase enzymes with widely differing structural, chemical, and physical characteristics. Furthermore, the genus is highly variable because a significant number of structural differences between genus members is permitted.

The specification discloses fucosidase, mannosidase, xylosidase, glucosidase, galactosidase, N-acetylglucosaminidase, and hexosaminidase from *Xanthomonas manhotis* and *Xanthomonas holcicola*. However, the specification fails to provide a written description of additional exoglycosidase enzymes as encompassed by the claimed genus. Neither the specification nor the general knowledge of those skilled in the art provide evidence of any significant amino acid sequence and structure of the recited exoglycosidase enzymes which would be expected to be common to the members of the genus.

In view of the above considerations, one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by members of the genus. Accordingly, Applicant has failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicant was in possession of the claimed invention.

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Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ichikawa et al. (Anal Biochem. 1992 May 1;202(2):215-38) in view Frank et al. (Applied and Environmental Microbiology (1979), 38(3), 554-6) and Su et al. (Journal of Biotechnology (1989), 9(2), 139-52).

Ichikawa et al. review methods for enzyme-catalyzed oligosaccharide and carbohydrate synthesis using a fucosidase, mannosidase, xylosidase, glucosidase, galactosidase, N-acetylglucosaminidase, or hexosaminidase which cleaves at a selected glycosidic bond between constituent monosaccharides of the carbohydrate thereby producing a modified carbohydrate which may then be subjected to other enzymes for the purposes of making other carbohydrates (see entire publication, especially pp. 228-235). Furthermore, Ichikawa et al. teach that the advantage of using glycosidases instead of glycosyltransferases is that expensive sugar donors are not required to achieve reaction; and that glycosidases are generally more available and less expensive than glycosyltransferases (see p. 228, right column, lines 20-25). The teachings of Ichikawa et al. differ from the claims in that the claims instead recite *Xanthomonas* glycosidases.

Frank et al. teach beta-galactosidase from *Xanthomonas campestris* and its general properties (see entire publication).

Su et al. teach the cloning and expression of a beta-glucosidase from *Xanthomonas albilineans* (see entire publication).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Ichikawa et al. such that the beta-galactosidase from *Xanthomonas campestris* as taught by Frank et al. or the beta-glucosidase from *Xanthomonas albilineans* as taught by Su et al. is contacted with a suitable carbohydrate substrate in order to produce a modified carbohydrate product which inherently would have immunogenic properties that are different or altered compared to the original carbohydrate substrate.

One of ordinary skill in the art at the time the invention was made would have been

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motivated to do this because Ichikawa et al. teach that the advantage of using glycosidases instead of glycosyltransferases is that expensive sugar donors are not required to achieve reaction; and that glycosidases are generally more available and less expensive than glycosyltransferases

Thus, the claimed invention was within the ordinary skill in the art to make and use at the time was made, and was as a whole clearly prima facie obvious.

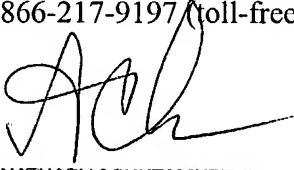
Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600